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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,045	01/26/2001	Jonathan P. Duvick	1134C	7253

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,045

Applicant(s)

DUVICK ET AL.

Examiner

Medina A Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 20- 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 5/16/03 in reply to the Office action mailed 1/13/03 has been entered. Claims 1-22 are pending. Claims 1-8 and 12-19 are examined. Claims 9-11 and 20-22 are withdrawn from consideration. The terminal disclaimer filed on 5/16/03 has been reviewed and is accepted. The terminal disclaimer has been recorded.

All previous rejections and objections not stated below have been withdrawn.

New Matter

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The claims recite an isolated polynucleotide comprising at least 200 contiguous bases of SEQ ID NO: 35 encoding a protein having fumonisin degrading activity, a plant cell, a plant and seed comprising said polynucleotide. However, support for the "200 contiguous bases" cannot be found in the specification or in the claims as originally filed. Therefore, the "200 contiguous bases" is considered to be a new matter.

Applicant is requested to point to support for the phrase in the originally filed or to delete the NEW MATTER in response to this rejection.

Claim Objections

In claim 8, ----degrading--- should be inserted after "fumonisin", in line 2.

Claim Rejections - 35 USC § 112

Claims 1-8 and 12-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polynucleotide of SEQ ID NO: 35 and a sequence having at least 90% or 95% sequence identity thereto and encoding a protein having the fumonisin degrading enzyme of APAO, transgenic plant/plant cell/seed comprising said polynucleotide, does not reasonably provide enablement for any polynucleotide comprising at least 200 contiguous bases of SEQ ID NO: 35, any polynucleotide that hybridizes thereto under the defined high stringency conditions and encoding a protein having fumonisin degrading activity, and transformed plants/plant cells/seed comprising said polynucleotide . This rejection is repeated for the reasons of record as set forth in the Office action of 1/13/03. Applicant's arguments filed 05/16/03 addressed the rejection to polynucleotides having at least 90% and 95% sequence identity to SEQ ID NO: 35 and encoding APAO, but do not address the rejection to fragments of at least 200 contiguous bases of SEQ ID NO: 35 and polynucleotides that hybridize thereto under high stringent conditions.

Applicant 's arguments regarding polynucleotides having at least 90% or 95% sequence identity to SEQ ID NO: 35 and encoding a protein having fumonisin degrading activity are found persuasive, since APAO polynucleotides including polynucleotides that are at least 90% sequence identity to SEQ ID NO: 35, from different sources are

disclosed in the specification and in parent applications 09/352, 159 and 09/352, 168, now US patents 6, 211, 434 and 6, 211, 435, respectively.

The claimed polynucleotides comprising at least 200 contiguous bases of SEQ ID NO: 35 and those that hybridize to SEQ ID NO: 35 under high stringent conditions and still encoding a protein having fumonisin degrading activity are not supported by an enabling disclosure taking into account the *In re Wands* factors disclosed in the last Office action. Applicant has not taught that every 200 contiguous bases of SEQ ID NO: 35 has the ability to encode a functional polypeptide having fumonisin degrading activity, and that it can be used for the production of transgenic plants having resistance against fumonisin producing fungi. Applicant has provided no guidance with respect to regions of the full-length polynucleotide sequence that are sufficient to produce functional polypeptides. Absent such guidance, one skilled in the art would have to make all possible 200 contiguous bases of the 1920 nucleotides of SEQ ID NO: 35 and test all polynucleotides that meet the structural limitations to determine which also meet the functional limitation. One skilled in the art would also have to determine which of these polynucleotides that meet both the structural and functional limitations could be used for the production of transgenic plants and seed having the desired fumonisin resistance phenotype.

Applicant has not provided guidance for a polynucleotide that hybridizes to SEQ ID NO: 35 under Applicant's high stringency conditions and still encoding APAO. Neither Applicant's response nor the prior art provides evidence that the hybridizing property of a polynucleotide is sufficient for a skilled artisan to predict the function of said

polynucleotide. Therefore, it is unpredictable if any and all polynucleotides that hybridize to SEQ ID NO: 35 under high stringency conditions would encode a polypeptide having the APAO activity and specificity. If the encoded protein is not functional or does not have the desired function, then one skilled in the art would not be able to use the claimed polynucleotide to produce transgenic plant/seed having the desired agronomic phenotype. In addition, the high stringency conditions as recited in the claims do not specify "time", and therefore, it is unpredictable if most or all the resultant polynucleotides will be APAO. Therefore, in view of *In re Wands* factors as discussed in the last Office action, it is concluded that the teachings of the specification are not commensurate with the broad scope of the claims, and therefore, the claims are not enabled throughout the broad scope.

Applicant has not specifically addressed the rejection to fragments and hybridizing sequences, and the claims as amended do not overcome the rejection. Therefore, the rejection is maintained.

Written Description

Claims 1-8 and 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the Office action of 1/13/03. Applicant's arguments filed 05/16/03 addressed the rejection to polynucleotides having at least 90% and 95% sequence identity to SEQ ID NO: 35, but do not specifically address

polynucleotides that hybridize to SEQ ID NO: 35 under high stringent conditions or polynucleotides comprising at least 200 contiguous bases of SEQ ID NO: 35, and encoding a protein having fumonisin degrading activity.

The claims drawn to isolated polynucleotides that hybridize to SEQ ID NO: 35 under high stringency conditions and polynucleotides comprising at least 200 contiguous bases of SEQ ID NO: 35, and encoding a protein having fumonisin degrading activity are not adequately described because Applicant has not described representative species of the genus of the claims. Applicant has described regions of the full-length polynucleotide sequence that are sufficient to produce functional protein, and therefore, every 200 contiguous bases of SEQ ID NO: 35 are not expected to encode a functional protein. In addition, a substantial variation in structures and function are expected among polynucleotides that share 200 contiguous bases because every 200 contiguous bases of SEQ ID NO: 35 are not disclosed as being specific for APAO. Since Applicant has not described the polynucleotides of the invention, the recombinant expression cassette, transformed plants, plant cells and seed comprising the polynucleotide are similarly not described. Note, the generic claim of Example 14 of the Revised Interim Written Description Guidelines does not support Applicant's claims drawn to fragments and hybridizing sequences.

Therefore, weighing all the factors above and in the last Office action, the written description requirement of polynucleotides comprising at least 200 contiguous bases of SEQ ID NO: 35 and polynucleotides hybridizing thereto under high stringent conditions

encoding APAO, and vectors, transgenic plants, plant cells and seed comprising said polynucleotides is not satisfied.

Applicant has not specifically addressed the rejection to fragments and hybridizing sequences, and the claims as amended do not overcome the rejection. Therefore, the rejection is maintained.

Remarks

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday from 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

8/1/03

Mai

A handwritten signature in black ink, appearing to read "Amy Nelson", written in a cursive style.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600